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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,529	09/10/2003	Cary James Miller	215105.01500	5356

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PATENT ADMINISTRATOR
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EXAMINER	
YU, MELANIE J	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/658,529	MILLER ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-7,9-12,69 and 70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-7,9-12,69 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 3 January 2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 2, 5-7 and 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that a first immunosensor generates a signal based on the formation of a sandwich between an immobilized antibody, a target analyte and a labeled antibody. It is unclear as to whether the immunosensor system requires an immobilized antibody, a target analyte and a labeled antibody in the form of a sandwich, or whether the immunosensor merely requires a sensor that is capable of generating a signal based on a sandwich.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 9, 11, 12 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Piran et al. (US 6,087,088).

Piran et al. teach an immunosensor system comprising: a first immunosensor that generates a signal based on the formation of a sandwich between an immobilized antibody, a target analyte and a labeled antibody, wherein a portion of the signal arises from non-

specific binding of the labeled antibody in the region of the first immunosensor (antibody to the analyte is immobilized to the first immunosensor and the analyte and a labeled antibody form a complex, first antibody to analyte, col. 4, lines 27-30; target analyte bound with specific labeled probe, col. 5, lines 1-5; a label is specific for and binds to analyte, col. 5, lines 8-12; sandwich immunoassay, col. 6, lines 3-5; analyte TSH binds to immobilized anti-TSH and label binds to TSH, col. 6, lines 10-24); and a second immunosensor that acts as an immuno-reference sensor and generates a signal that is the same as the non-specific binding that occurs in the first immunosensor signal (second immunosensor is used as a reference and is used to adjust the signal of the first immunosensor for non-specific binding, reference signal mathematically corrects the signal from first labeled antibody, col. 4, lines 40-47), and has an immunocomplex between an immobilized antibody and an endogenous or exogenous protein that is in the sample and is not the target analyte (antibody to IgG is immobilized on the second immunosensor and IgG is an endogenous or exogenous protein, anti-IgG is used for calibration purposes, col. 5, lines 59-67; col. 7, lines 44-67).

With respect to claim 11, Piran et al. teach both antibodies immobilized on microparticles with a diameter that varies from 10 nm to several microns in diameter (col. 7, lines 11-15), which is partially encompassed by the recited range of 0.01-5.0 μm in diameter.

With respect to claims 9, 12 and 69, the claims are drawn to the properties of a sample to be tested in the immunosensor system, the concentration of endogenous or exogenous protein in a sample and the type of sample. While the prior art does not specifically recite the concentration of protein in the sample as claimed, such a limitation is merely an intended use which the prior art would inherently be capable of doing. The only distinction between applicant's claims and the prior art is recited in the functional language. It is incumbent upon applicant to show that the application disclosed by Piran et al. is not

actually capable of performing such functions. See *In re Ludtke 1971*, 169 USPQ 563 (CCPA 1971) and *In re Swinhartetal*, 169 USPQ 226 (CCPA 1971).

4. Claims 1, 2, 5-7, 9, 10, 12, 69 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Ding et al. (US 2001/0029048) in light of Lee et al. (US 4,722,889).

Ding et al. teach an immunosensor system comprising: a first immunosensor that generates a signal based on the formation of a sandwich between an immobilized antibody, a target analyte and a labeled antibody (first electrode has immobilized antibody, analyte and labeled antibody form sandwich assay, par. 22, 24 and 25, first analyte may be hCG, par. 20), and a second immunosensor comprising an immunocomplex between an immobilized antibody and an endogenous or exogenous protein that is in the sample but not the target analyte (second electrode detects second analyte which may be an endogenous or exogenous protein, IgG, par. 18-20, second electrode has immobilized antibody and protein binds to immobilized antibody, par. 22-25). Although Ding et al. does not specifically teach the portion of the first signal arising from non-specific binding of the labeled antibody in the region of the first immunosensor, Lee et al. teach that other components in a fluid may non-specifically bind with antibodies specific for hCG (col. 1, lines 29-40). Therefore, at least a portion of the signal arising from the first immunosensor of Ding et al. is from non-specific binding. Furthermore, the instant specification teaches that an antibody that binds to plasma proteins is suitable for generating a signal that is the same or related to the degree of non-specific binding in the region of the first immunosensor at page 18, paragraph 85. Ding et al. teach an antibody that binds to fibrinogen (a plasma protein) and therefore generates a signal that is the same or related to the degree of non-specific binding in the first immunosensor region.

With respect to claim 2, Ding et al. teach the first and second immunosensors being electrochemical (par. 21).

Regarding claims 5-7, Ding et al. teach the immunosensor contained in an electroanalytical cell made of Teflon (par. 9, 22), which is a cartridge, and a cell is capable of being disposed, and is therefore disposable. Ding et al. also teach the target analyte being hCG (par. 20) and the immobilized antibody in the second immunosensor being to a plasma protein (fibrinogen, par. 20, is a plasma protein).

With respect to claim 10, the instant specification teaches that antibodies to analyte of fibrinogen having an acceptable affinity constant within the range of about 1x10(-7) to about 1x10(-15) at page 19, paragraph 85. Ding et al. teach an analyte of fibrinogen (par. 20) and an antibody that binds to the analyte (par. 14). Therefore according to the instant specification, the antibody to fibrinogen has an affinity within the recited range.

Regarding claims 9, 12, 69 and 70, the claims are drawn to the properties of a sample to be tested in the immunosensor system, the concentration of endogenous or exogenous protein in a sample and the type of sample. While the prior art does not specifically recite the concentration of protein in the sample as claimed, such a limitation is merely an intended use which the prior art would inherently be capable of doing. The only distinction between applicant's claims and the prior art is recited in the functional language. It is incumbent upon applicant to show that the application disclosed by Ding et al. is not actually capable of performing such functions. See *In re Ludtke 1971*, 169 USPQ 563 (CCPA 1971) and *In re Swinhartetal*, 169 USPQ 226 (CCPA 1971).

Response to Arguments

5. Applicant's arguments filed 3 January 2007 have been fully considered but they are not persuasive.

At pages 4-11, applicant argues the rejection under 35 USC 112, second paragraph. Applicant argues that regarding the rejection of the clarity of whether the immunosensor

system requires an immobilized antibody, target analyte and labeled antibody, the MPEP states that "examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement", and therefore the claim recites what is required. Applicant also argues that the present application teaches that the signal generated by the first immunosensor is based on the formation of a sandwich between an immobilized antibody, target analyte and a labeled antibody and therefore the claims recite what is required. Applicant's arguments are not persuasive because they do not attempt to clarify the claim language recited in claim 1. Claim 1 requires a first immunosensor that is capable of generating a signal based on the formation of a sandwich between an immobilized antibody, target analyte and labeled antibody, but does not recite whether the elements of the sandwich (immobilized antibody, target analyte and labeled antibody) are specifically required for the immunosensor system or whether the first immunosensor must merely be capable of generating a signal from these elements. The claim remains unclear.

At pages 12-20, applicant argues the rejections under 35 USC 102(b). Regarding the rejection of Piran, applicant argues that Piran fails to teach a second immunosensor that generates a signal that is the same or predictably related to the non-specific binding signal because Piran teaches two different labels while the present inventions teaches one label. Applicants argument is not persuasive because the claim language of claim 1, "comprising", is open and does not exclude other elements from the system, and therefore does not exclude a second label on the second sensor that is different from the label on the first sensor. Applicant further argues that the technique of eliminating interferences of Piran is completely different from the instant invention. This argument is not persuasive because the system of Piran teaches the recited elements of claim 1 and the claim is drawn to a

product claim, therefore different methods of using the systems, alone, does not render the claim free of the prior art.

Applicant argues that since the office argues that Ding does not specifically teach "a portion of the first signal rising from non-specific binding of the labeled antibody in the region of the first immunosensor" the claim does not teach the second immunosensor that acts as an immuno-reference sensor and generates a signal that is the same as or predictably related to the degree of non-specific binding which occurs in the region of the first immunosensor. Applicant states that according to the MPEP, a claim is anticipated only if each and every element as set forth in the claim is either expressly or inherently described in a single prior art reference. Applicant further improperly argues the rejection as a rejection under 35 USC 103(a) and argues that the examiner fails to provide motivation to combine Ding et al. with Lee. Applicant's arguments are not persuasive because the rejection is an inherency rejection made under 35 USC 102(b) and motivation is not required to combine references. According to MPEP § 2131.01:

> Normally, only one reference should be used in making a rejection under 35 U.S.C. 102.
> However, a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:
> (A) Prove the primary reference contains an "enabled disclosure; "
> (B) Explain the meaning of a term used in the primary reference; or
> (C) Show that a characteristic not disclosed in the reference is inherent.
>
> "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."

In the instant rejection, Lee is relied upon to show an inherent feature not disclosed by Ding et al. Ding et al. do not specifically state that a portion of the signal from the first immunosensor is due to non-specific binding. However, when binding occurs non-specific

binding inherently occurs absent any measures to prevent non-specific binding. Lee et al. is relied upon to show that this feature is inherent in a binding assay.

Regarding the rejection of Ding et al. in view of Lee, applicant further argues that the examiner uses impermissible hindsight reasoning to reach the conclusion of obviousness. Applicant's argument is not persuasive because this argument is only a valid argument for obviousness rejections under 35 USC 103(a) and the instant rejection is under 35 USC 102(b) and is therefore not applicable. However, for clarification purposes, applicant's disclosure is relied upon to show the inherency of a portion of the signal of Ding et al. being from non-specific binding and is therefore not relied upon for any disclosure of art.

Conclusion

No claims are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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